Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal

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Abstract

In recent years, there has been a rise in the creation of DNA databases promising a range of health benefits to individuals and populations. This development has been accompanied by an interest in, and concern for the ethical, legal and social aspects of such collections. In terms of policy solutions, much of the focus of these debates has tended to be on issues of consent, confidentiality and research governance. However, there are broader concerns, such as those associated with commercialisation, which cannot be adequately addressed by these means. In this article, we focus on the health-wealth benefits that DNA databases promise. As in previous studies, our qualitative research on public/s and stakeholders' views of DNA databases show the prospect of utilising donated samples and information derived for ends that are wealth-related (i.e. for private profit), irrespective of whether there is an associated health-related benefit, arouses considerable reaction. While health-wealth benefits are *not* mutually exclusive ideals, the tendency has been to cast 'public' benefits as exclusively health-related, while 'private' commercial benefits for funders and/or researchers are held out as a necessary pay-off. We argue for a less polarised approach that reconsiders what is meant by 'public benefits' and questions the exclusivity of commercial interests. We

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believe accommodation can be achieved via the mobilisation of a grass roots solution known as ‘benefit-sharing’ or a ‘profit pay-off’. We propose a sociologically informed model that has a pragmatic, legal framework which responds seriously to public concerns.

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Introduction

In this article we examine the recent international trend of creating DNA databases and ask, 'What should be done with any (monetary) benefits that arise from these endeavours?' Since the mapping of the human genome, there has been a significant increase in research into the role of genetic factors in the aetiology of complex diseases. DNA databases are constructed for such research and are defined as:

> …large-scale banks which contain either tissue samples, from which genetic material might be or has been extracted or genetic information, which may be coded and stored in various forms; and in addition, health and 'lifestyle' information pertaining to the sample donors (Williams and Schroeder 2004: 90).

In most population or disease-based DNA databases, individuals are asked to donate their DNA, to provide information on their lifestyle, and to allow researchers access to information held on their medical records throughout the life course. People are expected to donate their DNA material voluntarily, often anonymously, and without expectation of any direct benefit to themselves; any benefit is to some unknown other in the future. There is an institutionalised tendency to talk of the contribution of the public as a 'gift' with all the assumptions that this entails, i.e., that it is given freely and for no return. For example, the MRC Guidelines recommend, in light of legal uncertainty about who or in what circumstances one can 'own' human biological material, that tissue samples should be treated as conditional gifts or donations (MRC Guidelines 2001: 8).

We review previous research and thinking on the social and ethical issues relating to DNA databases with a particular focus on issues of profit and commercialisation. After reviewing previous consultations, we then present findings from research we conducted with a range of public/s about a proposed Scottish DNA database called 'Generation Scotland'. Here, we outline our methods and present our analysis around the following themes of; (i) access, (ii) ownership, and (iii) control. We then broaden our discussion to consider the morality of economic input before presenting a proposed solution to the problem of profits through a 'benefit share' model. In concluding, we consider whether we are witnessing the end of the traditional gift relationship between participant and researcher and suggest that legal solutions can be grounded in public concerns.

Promise and Profits

DNA databases promise future health benefits to individuals, families and whole communities. However, such promises are vague with an indefinite future time frame. A degree of controversy has surrounded the scientific value of some of these projects, with doubts expressed in various quarters as to whether these 'promises' can ever be realised (Barbour, 2003). Nevertheless, expectations of future benefit help shape the scientific domain and participant motivation. This promise is, explicitly or implicitly, relied upon by scientists involved in the projects whenever they speak of engaging with the public.

Like the notions of ‘gift’ and ‘gifting’, there is likely to be cultural variation around expectations about what a benefit is, as well as differences in the way benefits can be delivered (Wilson 2004). For example, the HUGO Ethics Committee defines individual and community benefit as social goods:

> A benefit is a good that contributes to the well being of an individual and/or a given community (e.g. by region, tribe, disease-group…). Benefits transcend avoidance of harm (non-maleficence) in so far as they promote the welfare of an individual and/or a community. Thus, a benefit is not identical with profit in the monetary or economic sense. Determining a benefit depends on needs, values, priorities and cultural expectations (HUGO Ethics Committee, 2000).

These social goods do not include direct monetary return to participants. Indeed, HUGO states there should be no financial gain from participation in genetic research. The organisation does not, however, preclude potential monetary return to others. In this view, ‘benefits’ divide along blurred, yet discernible lines: ‘public’ benefits in the form of (potential) public health improvement and ‘private’ benefits in the form of (potential) private commercial gain. Generally, this is viewed as potential future health improvements, through research into the prevention, diagnosis and treatment of illness and disease; however, it may also include potential improvement to the health infrastructure. Aside from rewards to the scientific community of academic and commercial return, there are at least two discourses of ‘promise’ at play: the promise to

the public of better health and the promise to private parties of commercial reward for their efforts.

A large part of making the wider health benefits a reality is the involvement of commercial and pharmaceutical companies. It is argued that commercial companies should be granted access and that they should be entitled to seek exclusive rights over the products of their work with the data or samples from DNA databases. It is only by these means will new drug therapies or health benefits be realised. On the other hand, authors have commented on the importance of open and free access for knowledge creation (Marks and Steinberg, 2002). The *necessity* of commercialisation is therefore a disputed matter however it is the *prospect* of such commercialisation that is of interest to us.

At present, there are no plans in the UK to allow any single company access to DNA databases such as the UK Biobank or Generation Scotland; this is to be contrasted with the Icelandic Health Sector Database where Decode Genetics was granted an exclusive licence (Merz, McGee, & Sankar, 2004). Rather, in the UK, it has been stated as a matter of policy that the information and samples will be held in 'custodianship' or 'stewardship' by the research governance bodies. Yet both UK projects envisage that data will be available to commercial companies, which might, then, become the subject of further exploitation and/or (intellectual) property rights. There is little in the world's intellectual property systems to prevent commercial companies seeking intellectual property rights over downstream products developed using a DNA database resource.

Space restrictions do not permit the luxury of a full discussion here, but the conclusion is clear. That is, reforms responding to public concerns about commercialisation will not emerge from within existing property regimes.

Profit and the public/s

Available research shows people have strong views about genetic research (Hoeyer 2004) and the involvement of commercial companies is a contentious issue that has generated some public resistance. This may affect individuals' willingness to participate, although reactions vary between groups and individuals and even within single discussions (Cragg Ross Dawson. 2000; Haddow, Cunningham-Burley et al. 2005). The Wellcome Trust and the Medical Research Council (supported by the Department of Health) funded social research on people's views about the collection of biological samples (now UK Biobank). Cragg Ross and Dawson's (2000) sixteen focus groups showed critical attitudes towards pharmaceutical companies based on the 'questionable ethics' of combining money and medicine. Their respondents who were less critical of pharmaceutical companies tended to have experience of chronic illness and viewed such companies as sources of potential cures. Other participants balanced more general criticisms of companies in light of an outcome for the "common good". Some were under the mistaken belief that a pharmaceutical company was planning the DNA database (the medical charity, The Wellcome Trust, was confused with Glaxo Wellcome). Once it was made clear the project would be publicly funded this was said to be 'reassuring and important in communicating its (the DNA databank's) credibility'

(ibid p.9). Later research also showed that commercial companies' access was to be blocked on the grounds they are 'getting something for nothing' (People Science and Policy Ltd. 2002).

Representative surveys demonstrate that regardless of whether commercial companies had made a significant expenditure in generating new ways to use genetic information, over 70% said that this information was still to be 'publicly owned' and made available to all for no charge (Human Genetics Commission 2001: 27). To show how important pharmaceutical access was in inhibiting potential participation, Hapgood, McCabe et al (2004) employed the controversial 'discrete choice experiment' model, asking their 1238 survey participants to choose the biobank model in which they would prefer to participate. The most important impediment affecting participation was access by pharmaceutical and insurance companies (Hapgood, McCabe et al. 2004). Contrary to such findings, other research found that once the need for commercial access was 'adequately explained' most people were happy to participate. Jack and Womack (2003) found only 2 refusals of 3 140 preoperative tissue donors.

Previous research shows ambivalence, reluctance and suspicion at the prospect of commercial companies becoming involved in DNA databases although research highlights that such views are variable (i.e., between patient groups and other public/s) and can shift from initial negativity to ambivalence. This leads to the persistence of doubts as to whether people will participate or donate 'freely' when commercial entities are involved, although hitherto research with diverse publics has not proffered solutions

to this ambivalence. So, we now turn to consider our own findings and possible solutions based on participants' own suggestions.

Methods

Our aim was to conduct an exploration of opinions about the development of Scotland's first national genetic database, Generation Scotland, with special attention to views on how the research organisation might develop and what form it might have. Generation Scotland is an initiative in its conceptual and developmental stage, but will involve a family-based genetic database to research common diseases. Consideration of and response to social, legal and ethical issues are being incorporated from the start of the project. As a starting point for this joint working, in January – March 2004, ten focus groups, chosen to reflect a range of demographics (gender, ethnicity, and age), interests (patient, voluntary and civic groups), and localities (rural, semi-rural or urban) were undertaken (see Box 1). All had a social researcher as a moderator to conduct the discussions and most had a rapporteur responsible for writing notes and capturing key points. Most were tape-recorded and transcribed, fully or partially, for subsequent thematic analysis along with the rapporteur's notes. We asked questions that would generate discussion on participation, recruitment, withdrawal, access, consent, feedback, public engagement, and confidentiality.

The analysis of transcripts began inductively with transcripts and accompanying notes being read closely by the researchers and then sorted into themes. We then generated

key themes and returned to each for further detailed analysis within and across topics. During discussions we encouraged participants to raise issues themselves, to be candid about their concerns and to draw specifically on their own interests as well as provide more general comment. We deliberately sought not to lead the discussion or influence the participant's opinion. Earlier consultations have been criticised on several grounds but mainly for taking a 'deficit model' approach to the discussion whereby it was seen to be more important to educate and gather views than to allow the participants the freedom to frame the debate (Wakeford and Hale 2004). The success of our open ended approach was variable and highlights the difficulties of conducting research 'upstream' (Wilsdon & Willis, 2004). At times, the questions led to respondent frustration at the moderators, for example, 'What are the options?'(FG1 R3), and 'I don't know. I don't know enough yet' (FG1 R2), a situation perhaps created by early consultation of a research project 'in the making'. Some individuals and groups spontaneously brought up concern about commercial company access whilst others did so in response to our further probing. When we raised the question of patenting, there seemed to be a lack of understanding and confidence about discussing this in the groups.

Although this was a small scale exploratory study intended to raise issues for further consideration as the public consultation developed, we obtained some indication of what benefits the publics would want and would also tolerate. The findings have some similarity with other public consultations referred to earlier. However, we offer further understanding about why commercial access seems to provoke ambivalent reactions in different public groups.

Findings

We discuss our findings around three broad themes of; (i) access, (ii) public ownership and governance, and (iii) control using illustrative quotations and examining diverse opinions where expressed.

Who should be allowed access?

The focus group discussions about the aims of Generation Scotland were positive and there was evidence of willingness to participate with accounts replete with references to welfare and collectivism – for the 'common good' and the 'future of society'. Findings are consistent with other work that found resistance to allowing commercial companies access to DNA database resources. There was evidence of differences in views between the patient and carer groups (for example those affected by Cystic Fibrosis or Multiple Sclerosis) and other civic or area based groups recruited into the study (such as members of a local choir or sports club). The patient groups in this sample tended to be more willing to accept pharmaceutical involvement as a 'necessary evil' and suggested greater personal motivation to participate as the following quotation illustrates:

People have obviously got, when you've got somebody that's got a condition in the family then they're more inclined to help. If you're talking to somebody sitting at the table who didn't have anybody in their family with anything wrong, 'why should I bother',

'I'm not going to gain anything out of this', this sort of thing. We've obviously got more something to gain somewhere down the line possibly, but somebody else might not have (FG1 R3).

Others discussed the importance of individual benefit to motivate people:

... *I think it's something that's very easy to do, giving human blood or giving a genetic blood group for genetic study. But people probably won't get off their backsides to do it unless there's a direct benefit to them* (FG3 R3).

There was a high level of agreement amongst the focus group participants about the 'vulnerability' of patient groups which, it was presumed, makes them more susceptible to the potential over-selling of the benefits, thereby raising questions about how participation might be ethically monitored. Other researchers have noted the distress caused by raising false hopes for those who suffer from life-threatening disease (Stockdale, 1999). Nonetheless, the patient groups in our sample seemed to be well aware of what, and where, the interests of the pharmaceutical companies lay (FG1, FG6):

Let's face it, drugs companies have got to make a profit. They don't make a profit, the money's not going to come back round again and back into research. So it's just a big wheel, it's got to be done, you can't turn round and say "stop making any money (FG1 R2).

There was a sentiment expressed by some in the CF group that pharmaceutical companies 'try to help out', despite the respondents also acknowledging that pharmaceutical company involvement was about selling drugs (FG1). Likewise, the MS group was sceptical of the 'oversell' or the 'talking up' by commercially interested parties promising a 'cure' for MS; they felt, however, that they had to place faith in them for, 'how else could a treatment be found?' Finally, in the Breast Cancer Support Group (FG4):

R3: I wouldn't like all the profits going….a sort of reciprocity…

R2: As long as some is put back into the health service, and finding out what can help.

R4: Of course if there's no companies doing the research it won't get done will it?

Despite recognising the need for pharmaceutical companies to develop drugs, the majority of our respondents said access to the DNA database should be restricted to medical personnel, academics or research scientists. This is not to be interpreted as a whole-hearted endorsement of public officials or researchers as demonstrated by comments such as, '…if they are clever enough to be doing this, they should be trusted because who else will be able to help?' suggest a relationship between trust and knowledge that was repeated in other groups. Without having 'faith', diseases like dementia would never be eradicated and 'nothing comes without some risk' (FG10, R3).

Our data show that, on the one hand, experience and involvement with commercial organisations appear to generate a more positive image of commercialisation although we do not go so far as to suggest that all patient or support groups would be pro-pharmaceutical involvement. On the other hand, those with no or little personal experience tended to construct a 'public = good; private = bad' equation, although there was trust in some public institutions and not others.

Governance: Public Ownership?

In their hope for cures, it seemed that patient groups might tolerate wealth benefits based on profit because of exposure to this process through previous experience as well as for the potential future health gains. In these cases, we asked, whether and in what circumstances would others do the same? The response suggests that it is not only the making of profit that is the issue, but also what is then done with it. The participants in our focus groups were creative and forthright about the possible solutions which all centred on themes of *public ownership* and *returning profits*. Many thought it was important that the DNA database be 'publicly owned' (or controlled by public servants), or at least, that there should be public or charitable representation and ethical oversight. Most felt Generation Scotland should be a public charity and that benefits would be community and publicly-based. The Dementia Carers' Group emphasised 'control' with the medical profession acting as 'gatekeepers'. They suggested a 'trustee' of the people who support Generation Scotland could control it but not councillors, politicians or pharmaceutical company personnel. Or, as another group suggests,

Generation Scotland could be an independent trust that 'owns' the database and licenses pharmaceutical companies to do work (FG 3). In fact, several alternative solutions about who should control access were offered including the Scottish Executive, NHS or universities.

Control

Despite varying ideas about who should be in control, the issue of control appeared key to resolving ambivalence about access. Some argued that the consent of those able to give it should be gained at the point of donation as the person loses 'control' over the DNA sample post-donation (FG4):

I can see how once you've given up the blood it would be difficult to keep control of what happens to it and so on. But I would hope that there would be ethical safeguards built into you dealing with it and companies would have to meet a certain standard and so on (R1).

In another group one respondent suggested:

The very worst case scenario is you get things like the Minority Report where it's scanning eye, they know everything about you and your most desires, and that's what they're starting to do with technology. Like this new passport they want you to have, different things on. So there's obviously certain things that you don't want it going too far, ***and you want control over your own things*** (emphasis added, FG1 R2)

We do not know what this respondent meant by ‘own’ or ‘ownership’ of the samples. Is he more concerned about property rights (i.e. ‘it is mine’) or about control (i.e. ‘I want to have a say in what you do with it’) or, indeed, both as there may not be a clear distinction between the two? In only two of our focus groups was the idea mooted that individuals owned their genes and therefore had a right to say what happened to them. Legal concepts of property allow the imposition of a raft of obligations but there is a dearth of evidence of whether individuals see ‘their’ sample as ‘their’ property. Indeed, the majority of respondents in this study suggested that the genetic data from the sample was ‘publicly owned’ and therefore was to be put to a use that contributed towards the common good and in accord with the principles of the UK National Health Service. Although the connection was not explicitly made, the strong support for the administration of the samples by a trusted (public) third party suggests to us, that the desire for control is expressed through notions of ‘public ownership’ of samples. This was a finding also evident in previous Swedish work that proposed a relationship between public ownership and control (Hoeyer 2004).

Further solutions to issues of access, control and profit were offered by our participants. For example, ‘[H]ealth’ said one of our respondents, ‘is universal, and should be reinvested back into the community and the people’ (FG 8). The participants were confident and creative when discussing a ‘profit pay-off’ with ideas ranging from cheaper drugs (FG3, FG6), monies going into public health (FG 4), back to research, NHS or charities linked to health (FG8) or into Scotland (FG2): .

R4: I think it should be given back to Scotland. Because then you're going to it's being regenerated, isn't it, and can be made more use of it. I don't think drug companies should make the profit.

R1: They make enough….

R4: I mean they're bound to get something.

R3: …and also for the good of the population.

R4: Absolutely.

This type of discussion was made repeatedly and spontaneously in the majority of groups and became a familiar concept to the focus group moderators.

It appears that commercialisation will be tolerated in two types of circumstances. First, by groups affected by disease when commercialisation is viewed as the necessary 'pay-off' to secure the promised health benefit to the community. Second, where there is '*public ownership'* and a '*profit pay-off*' by the researchers/profiteers in terms of offering a wealth benefit to the community. To date, however, the research governance model has been blind to the latter and treated the former as a universal norm. This may be an unsustainable position as we will go on to argue later.

Discussion

Blocked Exchanges, Moral Economies and Tolerating Commodification

There is obvious mistrust of the commercial imperative in health issues. The focus groups convened for this study provide exploratory accounts but not on-going

deliberation of emergent issues. Future forms of public engagement will provide such opportunities in the Scottish context. For us, the root of public ambivalence seems to lie in; (i) notions of justice and fairness about private profit being made through public exploitation, (ii) a perceived lack of control in terms of governance, and (iii) issues of identity and commodification whereby 'something is lost' and people are disrespected when commercialisation enters the picture.

Cultural expectations and representations of pharmaceutical companies are likely to influence public perceptions of them i.e., media reports of pharmaceutical companies' 'exploitation of those who are vulnerable or in need and the…priority of promoting products which maximise profitability over meeting the needs of poor communities.' (Davison et al. 1997, 334). Access to, and exploitation of new commodities such as genetic data is part of a continuing trend of commercialisation of the body (Nelkin 1995). Whilst we might contend it is not commercialisation of the body *per se* but rather the question of research using information (and samples) derived from human DNA, this is perhaps being unduly pedantic (Wilkinson 2005). Hoeyer (2004: 108) discusses the ambiguous qualities and multiple interpretations associated with the blood donated for DNA assay with some of his informants making statements that 'blood is just blood', while at other times strong associations were drawn between genes and personhood. In the UK, our bodies and matter from them (whether it be organs, blood or genetic material) have ambiguous representational meanings both as object and symbol (Titmuss 1970; Belk 1987; Belk 1990; Root Wolpe 1997; Hoeyer 2004; Haddow 2005).

Thus the progress of commodification and monetary domination can be limited by restricting the market and separating spheres of distribution (Walzer 1983). The present rejection of profit or commercial involvement with DNA databases can be linked to what has been conceptualised as the 'moral economy' (Thompson 1971). As others have more recently noted, economic activity depends on and is influenced by moral sentiments and vice versa (Sayer, 2004). Indeed, our focus group participants seemed to strive for an accommodation between what is considered profitable and what is for the common good. Our attention turns to how these 'moral economic solutions' can best be institutionalised.

A Benefit Sharing Model – The creation of new obligations?

As indicated, we suspect that 'property' and 'ownership' are being used by publics as metaphors for control. The need for control is related to the perceived need to counter *private* (property) rights with what seems to be their natural corollary of *public* (property) rights. Clearly, more work is required in this area, but as a team of social scientists and lawyers, we have tried to develop a sustainable solution from the views and suggestions offered in the focus group research. For reasons we articulate elsewhere, we do not advocate the creation of new property rights as this would be to miss the point (Laurie and Hunter, 2004). Rather we favour an approach which focuses on the public or community nature of this kind of research and endeavour to counter the perceived excesses of private profit. Analysing publics' motivations to participate helps greatly in identifying justifications for any new approach. We have seen, for example, that for patient groups the motivation is largely self-interest or, rather, the *health* interest of the

sector of the public affected by disease. However, for others, the motivation is far less obvious and the problem is that the privileging of the *wealth* interest of some might be impacting negatively on motivations of others to take part. Perpetuating property rights may simply replicate such patterns. The primary concern is consequentialist: it is to minimise the effects of private profit on participant recruitment. An obvious solution would be to remove the prospect of private profit altogether by denying intellectual property rights, but this would be draconian and ultimately against the public interest if it meant that research was simply not done. Moreover, publics generally accept the commercial realities of research. The underlying unease seems to be the sense that these are pursued at the expense of publics' interests. This raises related deontological considerations of fairness. Hence, the challenge is to devise an approach (i) which tempers, but does not unduly diminish, private financial interests in the name of the public good, (ii) which may act as an incentive to participate in research, and (iii) which can redress a perceived imbalance and serve to further a wider set of community interests. We contend that benefit sharing is an attractive model because:

1. It embodies a direct commitment to share profit and so directly addresses perceived injustices surrounding commercialisation (other legal mechanisms such as (public) property rights in samples would not necessarily achieve this);
2. It entails a commitment to justice which could go far in restoring some degree of public confidence in the research enterprise (even if people remain sceptical of for-profit involvement);

3. New obligations to share could easily be incorporated into the existing ethical approval framework with minimal disruption (see example below);
4. Research participants may have a role in influencing or directing sharing thereby reducing their passivity in the research exercise (discussed below);
5. It respects and recognises the status of DNA both as an object/subject that comes from individual research participants, but also for its communal or collective value and worth as a research tool and as a representation of a community interest in the outcomes of the research.

There has been extensive discussion in the literature of the rhetorical value of benefit sharing and a range of justifications have been proffered which reflect the consequentialist, deontological and pragmatic considerations we have identified above (Berg, 2001; Knoppers, 2000; Merz, Magnus, Cho, & Caplan, 2002; Simm, 2005). Our motivation, however, is to consider turning the rhetoric into reality.

As for the legal mechanisms that might be employed to achieve these ends, we already find an apposite example in the Newfoundland & Labrador model. The Provincial Approval Model of benefit sharing proposed by Pullman and Latus seeks to 'ensure a just allocation of the benefits that might accrue from human genetic research' (Pullman & Latus, 2002:1). Although designed to take account of the specific historical-political-economic circumstances of Newfoundland and Labrador, Canada, the principled reasoning behind the model is equally applicable to other contexts of benefit-sharing. Indeed, we endorse this framework as a practical example of how our findings and

arguments might be put into practice. The central element of the model is the requirement that anyone proposing to conduct research that includes a human genetic component must seek approval not only from an Ethics Committee (in the case of Newfoundland and Labrador, the Provincial Health Research Ethics Board (PHREB)), but also from a Standing Committee on Human Genetic Research (SCHGR). The researcher would be required to submit a proposal for benefit-sharing to the SCHGR, along with a rationale for the proposal, and final approval for the research project would only be granted if the Standing Committee were satisfied that an adequate benefit-sharing arrangement had been made in light of the following principles (Pullman & Latus, Report, 2003: 50; Pullman & Latus, 2002: 2):

1. Distributive justice: this requires that all legitimate stakeholders receive a fair share of both the benefits and burdens resulting from the research (begging the questions for the Committee, who is a 'legitimate stakeholder'? and what is a 'fair share'?);
2. Respecting the communal nature of the information contained in DNA: DNA should not be treated as a commodity to be owned, transferred, or otherwise exploited as a private, proprietary, good; while individuals will retain control over access to their own identifiable samples, the province has the responsibility of directing wider benefits in the name of the public good; and
3. Public administration and promotion of health as a common public good: "Benefit sharing arrangements that contribute to continued support of the health care

> system, to health care research in general, and/or to genetic research in particular will be especially encouraged" (Pullman & Latus, 2002: 3).

These authors caution against a 'one size fits all' approach to determining whether a benefit-sharing arrangement is reasonable or not, given the diversity of projects and the variability of the relative contributions to the success of the projects. They do, however, offer some general guidance on the form and content that benefit-sharing arrangements might take, beyond any potential health-related benefits. That is, benefit-sharing may be both 'in kind' (e.g. research facilities, equipment, jobs) and 'monetary' (royalties, percentage of gross profits etc.). While it is not recommended that monetary payment to individuals be outlawed, it is thought that a community-focussed regime would leave 'little reason' to pursue such practices. As far as can be anticipated in advance, the size of the benefit should be proportional to the significance of the contribution. Where the population [of the province] is projected to make a substantial contribution to some discovery, residents [of the province] should generally receive free access to any test or treatment (Pullman & Latus, Report, 2003: 53-54).

While this model has not been developed out of sociological findings in respect of the attitudes of the people of Newfoundland and Labrador, we suggest nonetheless it has considerable value because its structural approach reflects many of our findings about possible policy pathways. It is, for example, borne out of challenges to the altruism/gift model as well as more general concerns about the justice of the traditional approach. It also reflects the commonly-held view that DNA carries special significance from which

moral obligations flow when it is used/commercialised (Pullman & Latus, Report, 2003: 20). Finally, this approach complements, rather than supplants, existing regulatory mechanisms. Thus, it is proposed that participants are made aware, through the informed consent process, that the province will share in any financial benefits that may result from the research and that these benefits will be used to enhance health care and/or further health care research in the province. By the same token, it acknowledges that something is missing from our current regulations. It takes a community-focused approach to the question of *who* should share in benefits (and eschews individual contributions to participants as 'benefit'). It adopts an expansive notion of *what* counts as 'benefit' (reflecting our views above on the importance of recognising the community's interest in health and wealth benefits), and it adopts a casuistic approach to the question of *how* (and indeed whether) benefit sharing should take place. While one can quibble about particular details of the model (for example, the composition of the Standing Committee), we find merit in the attempt to institutionalise benefit sharing by placing the onus on researchers/profiteers to include a benefit sharing proposal as part of the entire governance framework.

An interesting phenomenon has accompanied the development of genetic research initiatives such as Generation Scotland and UK Biobank. We would call this a *Regulation-Plus* approach whereby additional scrutiny of the science and governance arrangements has been instituted, usually in tandem with a dedicated programme of ethical, legal and social research and often culminating in the establishment of some kind of oversight body which operates *in addition to* the standard ethical review mechanisms. Thus, UK Biobank has its Ethics and Governance Council, while

Generation Scotland has its Advisory Board established by the Scottish Executive in 2005. The reasons why this approach has been thought necessary are about responding to the changing social landscape of human genetic research. We contend that such bodies are ideally placed to recommend the adoption of benefit sharing arrangements as part of the *Regulation Plus* approach. The Generation Scotland Advisory Board is, for example, considering the arguments in this paper as we go to press.

The final obvious question is ‘how would such a model work in practice’? The outline of a viable approach is embodied in the work of Pullman & Latus, being typified by a central role for a brokering body. We would see this body having a dual role of (i) scrutinising benefit sharing proposals for ‘fairness’ (both to the community and to the researchers), and (ii) determining how benefits might be shared in the broader community. One might envisage, for example, the establishment of a fund, administered by this body, to which applications might be made by patient groups, advocacy groups, or even individuals, according to a set of agreed criteria for eligibility. Another approach might be a commitment by researchers to contribute benefits in kind in return for the privilege of working with public goods.

Scotland already operates precisely this model in the field of property development, known as the Private Finance Initiative or Public/Private Partnership model. In brief, this approach ties applications for planning permission to develop property with an obligation to make some broader contribution to the community in developmental terms.

For example, those seeking a contract to develop a particular public site must liaise with the state authority through a competitive process and may offer to build new roads or a school as the quid pro quo for securing the contract. All negotiations are confidential for all parties, acknowledging the important commercial interests at stake. The public always has a say in the planning permission process and plans are underway to overhaul this process to give an even greater say to the people. Space does not permit us to explore the exact parallels between this approach and the benefit sharing model that we advocate, but we would suggest that many of the practical objections so often raised against benefit sharing are addressed by a model that is already in practice. Obligations to benefit share would only become operational once profit over a certain limit was secured - there would therefore be no interference with intellectual property rights; commercial confidences would be respected as part of the overall structure of the system; the system itself would ensure tangible benefit to the public good, and the operational structure of the scheme would permit considerable flexibility and responsiveness in determining what could count as a benefit and who might be a recipient.

Conclusion

The implication of the findings and discussion presented in this article is that public participation based on the idea of *altruism* is questioned. The use of the language of altruism and gift conveys the notion that there will be no obligation on the part of the other parties in the relationship (the researchers/profiteers) beyond respecting subjects

in the course of their participation (which may amount to no more than the provision of a blood sample). It also ignores the variety of motivations and reasons that individuals have for participating in research or donating material and their interests in what happens next.

The essential concerns revealed by our research distil around the injustice of using a gift to make a profit, the lack of institutional control over that profit, and the perceived disrespect to people by the commercialisation process itself. We suggest that many of these concerns may be traced to the current institutional set-up governing population genetic and other medical research. This can be characterised as follows: i) research participants are largely passive in the research enterprise in the sense that they are expected to contribute source material but have little or no say in how that material is treated or used, ii) they do so on the basis of the so-called gift relationship and are imputed with altruistic motives, which, by definition, implies a lack of expectation of return, iii) researchers (and funders) have limited obligations beyond ensuring that participants are not harmed; community notions – or obligations – are excluded from the frame, and (iv) there is no viable mechanism within the governance framework to address concerns related to increased commercial activity. Whilst, historically, medical research and therapies have relied on the ‘gift’ model, this might not be appropriate in the present context as it no longer accurately reflects public attitudes towards the commercial realities of the research enterprise. Our research indicates that elements of the current approach are being challenged and that corrective action is required. The challenges include: i) the expanding phenomenon of patient and advocacy groups

which seek a more active role in genetic research, ii) the growing perception of injustice in respect of an institutional framework which, on the one hand, promotes participant altruism, and yet, on the other hand, sanctions third party commercialisation and private property rights, iii) the perceived inadequacy of regulatory control mechanisms which make no mention of ‘property’, and finally, iv) the suggestion that commercialisation practices can be ‘tolerated’ in certain circumstances.

Our motivation in writing this article stems from several sources; the first being a shared interest in seeing more interaction between our respective disciplines (law and sociology) towards common ends, as well as from the need, as we see it, to take a far more robust approach to public participation in policy formation than has occurred to date. We do not endorse a crude calculus that ‘what the public wants, the public should get’ nor should our proposals be taken as yet another example of a ‘fop’ to the public when policy is already well established. Rather, this is a genuine attempt to deploy social science research to reveal important policy pressure points, both as to the nature of a given problem and a possible acceptable solution. We have taken the ethos of public engagement seriously by attempting to institutionalise public solutions in a pragmatic legal resolution.

We believe that our research points towards a particular law and policy response for tackling concerns over commercialisation practices in the field. This is a model of benefit sharing that would form part of for-profit research endeavours using human genetic resources. Of course, policy considerations are always wide and varied. Thus, final policy solutions may only partially reflect public opinions and we do not claim that

our approach can avoid this. Far more research is required into public attitudes towards commercialisation – and benefit sharing – and we offer our experiences as a useful additional avenue of enquiry for interdisciplinary approaches to public engagement in the development of science and technology policy.

BOX 1.

Focus Groups:

Cystic Fibrosis Patient Support Group

Senior's Group

Cycling Club

Breast Cancer Advocacy Group

Rural Group

Multiple Sclerosis Support Group

Women's Hill walking Club

Sikh Sanjog Women's Group

Men's Choir

Dementia Carer Support Group

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